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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/492,763 | 01/27/2000 | Eiko Masatsuji | Q54487 | 1343 |

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| EXAMINER |
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KIM, VICKIE Y

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| ART UNIT | PAPER NUMBER |
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1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/492,763

Applicant(s)

MASATSUJI ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Status of Application

Acknowledgement is made of 132 declaration and remarks filed on 7/12/04. To antedate the prior art, 131 declaration with proper documents(e.g. lab note, etc) to prove applicant's own work that is earlier than the prior art of the record.

Response to Arguments

Until the proper declaration is filed, the rejection included in previous office action is maintained. Even if applicant's declaration antedates the prior art of the record(EP'321) and rejection over EP'321 is withdrawn, the art rejection issued on 5/16/03(paper no.20 ;102/103 over Sano(US 5,516,919) alone or alternatively, Sano in view of Fahim(US4372296)) is outstanding against pending claims 1-6.

Again, applicant is reminded that the instant claims examined are directed to a composition. Argument filed 9/16/03 is fully considered but they are not persuasive. As mentioned in previous office action, Sano'919 teaches a zinc salt of ascorbic acid -2-phosphate(APZ), as admitted by applicant's own remarks(see 10/9/2002 at page 3) . Applicants argued that Sano'919 fails to teach acne treatment. It is noted that the instant claims 1-6 are directed a composition comprising a therapeutically effective amount of APZ. rather than the use(e.g. acne treatment, reduction of skin irritation, etc). It is clearly stated in the court decision, applicant is not entitled to procure claims based on discovery that known composition of matter can be adapted to new use; to entitle him to patent, composition must both new and unobvious to one skilled in art. ***In re Hack***, 114 USPQ 161. Thus, the claims are maintained in the same rejection as follows.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Suzuki et al(EP884321).

The claims are drawn to a dermal agent comprising a therapeutically effective amount of a compound which is represented by the formula 3(as shown in instant claim 1).

Suzuki et al(EP'321, hereafter) teach a cosmetic or medical preparations that contains L-ascorbic acid 2-phosphate zinc salt as an active ingredients, see examples 3-4 at page 6. Thus, all the critical elements required by the instant claims are taught by the cited reference.

EP'321 also teaches about the antimicrobial effect and excellent stability accompanied by the active agent(i.e. L-ascorbic acid 2-phosphate zinc salt), see test examples 1-2, at page 5. EP'321 further teaches the intended use of the composition as antidandruff or antiseptic agent due to the said antimicrobial activity and the liberation of the active species(i.e. L-ascorbic acid) in vivo, see page 2, lines 28 and page 3, lines 1-3. Regardless of the said teachings such as liberation of active species(i.e. L-ascorbic acid) or antimicrobial activity, it is noted that all the limitations

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recited in the claims 2-6 are met inherently by the composition taught in the cited reference.

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sano et al(US 5,516,919) , or alternatively , as obvious over Sano et al(US 5,516,919) in view of Fahim(US 4,372,296).

The claims are drawn to a dermal agent comprising agent comprising a therapeutically effective amount (0.01-90%) of a zinc salt of ascorbic acid derivative represented by the formula (3).

Sano et al(US'919) teach a stable topical composition comprising a effective amount of metal salts of ascorbic acid-2-phosphate used in the field of cosmetics and medicines, see column 1, lines 5-10. US '919 also teaches its beneficial use in the cosmetic and pharmaceutical field where the salt of ascorbic -2-phosphate shown the superior quality than conventional ascorbic acid preparations. It further teaches salt formation process using zinc carbonate as a source for metal salt, see column 2, line

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31-32. Although Sano fails to exemplified specific example containing a zinc salt of ascorbic acid-2-phosphate, one would have been readily envisaged a zinc salt of ascorbic acid -2-phosphate as a final product resulted from said salt formation process when it is viewed by other examples. For instance, ammonium or magnesium salt of ascorbic acid-2-phosphate is produced by same salt formation process using ammonium solution or alkali metal(e.g. magnesium), see column 2, lines 29-34. The salt formation techniques are conventionally knowledge and also evidenced by Sano's patente, and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

Alternatively, even if said envision is not readily occurred, it would have been obvious to one of ordinary skill in the art to formulate the zinc salt of ascorbic acid-2-phosphate when Sano et al is taken in view of Fahim because Fahim teaches a topical composition containing a synergistic combination of zinc salt and ascorbic acid in acne treatment via stimulating collagen production and by killing the normal microflora(e.g. staphylococcus) found in the pilosebaceous ducts, see column 3, lines 7-37 and example 1.

Thus, one would have been motivated to use zinc carbonate to make a zinc salt of ascorbic acid -2-phosphate because that a zinc salt of ascorbic acid-2-phosphate have the synergistic combination of zinc ion and ascorbic acid and it maximizes the therapeutic efficacy while it reduces the skin irritation. Because of the synergistic combination requires small dose of each active agent, one could minimize the skin irritation that is caused by excessive amount of zinc or ascorbic acid. Nevertheless,

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achieving less skin irritations, inhibitory effect(staphylococcus, etc) recited in the preambles(claims 1-6) is inherent feature where it is naturally occurring when the therapeutically effective amount of a zinc salt of ascorbic acid –2-phosphate is applied topically. It is noted that a recitation of the intended use of the claimed invention, in case of the claimed invention is directed to the composition claims, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Thus the claimed subject matter is not patentably distinct over the prior art.

Conclusion

3. No claim is allowed.
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
5. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
June 13, 2005
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